

## REMARKS

This response is submitted in reply to the Office Action mailed September 3, 2008 ("the Action"). Claims 1-11, 14-26, 28, 29, 34-45 and 71-73 are pending in the application. Claims 8, 10, 11 53-55 and 70 stand as "withdrawn" from consideration.

### I. The Claim Informalities

The Action notes that Claims 17, 50 and 71 had certain claim informalities. Applicant has amended these claims to obviate these issues.

### II. The Art Rejections

The Action rejects Claims 1-7, 9, 14-26, 28, 29, 34-45, 47-52, 56-69 and 71-73 based on U.S. 2004/0092653 to Ruberti et al. ("Ruberti"). Ruberti proposes a one-piece prosthetic IVD of a polyvinyl polymer hydrogel (para. 27, 34). The Action alleges that as Ruberti says that the one-piece disk mimics the natural IVD, it inherently has the mechanical properties of the pending claims (Action, p. 3). Applicant respectfully disagrees.

### III. The Claims are patentable over Ruberti

Ruberti states that "the present invention provides a method of producing poly(vinyl alcohol) hydrogel that does not use chemical cross-linkers, irradiation or thermal cycling." (para. 68)(emphasis added). Indeed, Ruberti states that "PVA has generally not been considered for use as a load bearing biomaterial primarily because of its low modulus and poor wear characteristics." (para. 77)(emphasis added). Ruberti alleges that his proposed thetagels "broaden the range of functionality currently provided by PVA cyrogels." (para. 87)(emphasis added). Ruberti goes on to state, with respect to the freeze-thaw PVA, that as "cryogels are cross-linked by physical and not chemical means, there is some concern about their structural stability." (para. 89)(emphasis added). Ruberti also states that "there is very little information about the stability of PVA cryogel modulus under repeated load cycling (fatigue)." (para. 90). Notably, Ruberti also states that the freeze-thaw cycling of solutions of

PVA polymer "results in the formation of physical cross-links (i.e. weak bonding through an association of the polymer chains)." (para. 85, emphasis added).

Applicant agrees, as noted by the Action, that Ruberti does state at para. 14 that the PVA hydrogels can be **both** a thetagel and a cryogel. However, and notably, Ruberti clearly only teaches the use of cryogels (e.g., freeze-thaw thermal cycling), in combination with the thetagel processing. Stated differently, Ruberti requires either the thetagel alone, or both the thetagel processing **AND** the freeze thaw processing (not a material that is only physically crosslinked).

As noted above, Ruberti teaches that a freeze-thaw cryogel cross-linked only by physical and not chemical means is not suitable for IVDs due to "structural stability" issues or "fatigue".

As such, Applicant respectfully submits that Ruberti teaches away from implants/spinal discs formed only by freeze-thaw processing (e.g., that are only physically and not chemically cross-linked) to produce the mechanical properties. *See, e.g.,* Claims 1, 34, 43 and 63.

Applicant respectfully submits that the specification clearly supports the claim recitation that the interlocking mesh (physical cross-linking) is provided only by the freeze-thaw (thermal) cycling. *See* Example 1 of the pending application and U.S. Patent Nos. 5,981,826 ("the '826 patent) and 6,231,605 ("the '605 patent), which are incorporated by reference at page 11 of the pending application (for examples of methods of preparing elastomeric freeze-thaw cryogels). For example, both the '826 and '605 patents describe freezing and thawing to create an interlocking mesh of the PVA (col. 2) and that the freeze/thaw cycles produce the cross-linking rather than the use of cross-linking agents of the traditional cross-link (the '826 patent at col. 7, lines 55-62 and the '605 patent at col. 8, line 66, to col. 9, line 4).

Again, Ruberti teaches away from freeze-thaw processing (alone) of PVA cyrogel to produce the mechanical properties as claimed and the independent claims and the dependent claims which recite specific mechanical features produced by thermal cycling alone are patentable over Ruberti.

#### **IV. Ruberti Requires that the IVD have Anisotropic Properties**

In addition, Applicant submits that Ruberti emphasizes the gradient configuration of the devices and also states that any biomaterial "intended to replace the function of an intervertebral disk in its entirety must incorporate similar anisotropic properties." (see, para. 77)(emphasis added). While embodiments of the present invention allow for such a configuration, Example 1 does not require such a configuration as the same material processed in the same manner forms the IVD. For example, Claims 5, 40 and 74 recite that the body is monolithic. Applicant submits that at least these dependent claims are independently patentable over the cited art.

Applicant acknowledges that the Examiner stated in a prior Action (mailed 3/17/08, p. 3), the Examiner only objected to the use of the term "monolithic" in Claim 47 because if the core and annulus are distinct in terms of mechanical properties or composition, then the term "monolithic" is not appropriate. Applicant has used the term "monolithic" above to refer to the non-anisotropic property of the body, *e.g.*, that the PVA cryogel body has uniform properties.

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Application Serial No.: 10/658,932  
Filed: September 9, 2008  
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## CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Respectfully submitted,



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## CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on December 3, 2008.

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Cara L. Rose